

AMENDED IN SENATE MAY 31, 2016

SENATE BILL

No. 1095

Introduced by Senator Pan
(Coauthors: Senators Beall, McGuire, and Nielsen)

February 17, 2016

An act to amend Sections 124977 and 125001 of the Health and Safety Code, relating to public health, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

SB 1095, as amended, Pan. Newborn screening program.

Existing law requires the State Department of Public Health to establish a program for the development, provision, and evaluation of genetic disease testing.

Existing law establishes the continuously appropriated Genetic Disease Testing Fund (GDTF), consisting of fees paid for newborn screening tests, and states the intent of the Legislature that all costs of the genetic disease testing program be fully supported by fees paid for newborn screening tests, which are deposited in the GDTF. Existing law also authorizes moneys in the GDTF to be used for the expansion of the Genetic Disease Branch Screening Information System to include cystic fibrosis, biotinidase, severe combined immunodeficiency (SCID), and adrenoleukodystrophy (ALD) and exempts the expansion of contracts for this purpose from certain provisions of the Public Contract Code, the Government Code, and the State Administrative Manual, as specified.

This bill would require the department to expand statewide screening of newborns to include screening for any disease *that is detectable in blood samples* as soon as the disease is adopted by the federal

Recommended Uniform Screening Panel (RUSP). By expanding the purposes for which moneys from the fund may be expended, this bill would make an appropriation.

Vote: majority. Appropriation: yes. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Section 124977 of the Health and Safety Code
2 is amended to read:

3 124977. (a) It is the intent of the Legislature that, unless
4 otherwise specified, the genetic disease testing program carried
5 out pursuant to this chapter be fully supported from fees collected
6 for services provided by the program.

7 (b) (1) The department shall charge a fee to all payers for any
8 tests or activities performed pursuant to this chapter. The amount
9 of the fee shall be established by regulation and periodically
10 adjusted by the director in order to meet the costs of this chapter.
11 Notwithstanding any other law, any fees charged for prenatal
12 screening and followup services provided to persons enrolled in
13 the Medi-Cal program, health care service plan enrollees, or
14 persons covered by health insurance policies, shall be paid in full
15 and deposited in the Genetic Disease Testing Fund or the Birth
16 Defects Monitoring Program Fund consistent with this section.

17 (2) The department shall expeditiously undertake all steps
18 necessary to implement the fee collection process, including
19 personnel, contracts, and data processing, so as to initiate the fee
20 collection process at the earliest opportunity.

21 (3) Effective for services provided on and after July 1, 2002,
22 the department shall charge a fee to the hospital of birth, or, for
23 births not occurring in a hospital, to families of the newborn, for
24 newborn screening and followup services. The hospital of birth
25 and families of newborns born outside the hospital shall make
26 payment in full to the Genetic Disease Testing Fund. The
27 department shall not charge or bill Medi-Cal beneficiaries for
28 services provided under this chapter.

29 (4) (A) The department shall charge a fee for prenatal screening
30 to support the pregnancy blood sample storage, testing, and
31 research activities of the Birth Defects Monitoring Program.

1 (B) The prenatal screening fee for activities of the Birth Defects
2 Monitoring Program shall be ten dollars (\$10).

3 (5) The department shall set guidelines for invoicing, charging,
4 and collecting from approved researchers the amount necessary
5 to cover all expenses associated with research application requests
6 made under this section, data linkage, retrieval, data processing,
7 data entry, reinventory, and shipping of blood samples or their
8 components, and related data management.

9 (6) The only funds from the Genetic Disease Testing Fund that
10 may be used for the purpose of supporting the pregnancy blood
11 sample storage, testing, and research activities of the Birth Defects
12 Monitoring Program are those prenatal screening fees assessed
13 and collected prior to the creation of the Birth Defects Monitoring
14 Program Fund specifically to support those Birth Defects
15 Monitoring Program activities.

16 (7) The Birth Defects Monitoring Program Fund is hereby
17 created as a special fund in the State Treasury. Fee revenues that
18 are collected pursuant to paragraph (4) shall be deposited into the
19 fund and shall be available upon appropriation by the Legislature
20 to support the pregnancy blood sample storage, testing, and
21 research activities of the Birth Defects Monitoring Program.
22 Notwithstanding Section 16305.7 of the Government Code, interest
23 earned on funds in the Birth Defects Monitoring Program Fund
24 shall be deposited as revenue into the fund to support the Birth
25 Defects Monitoring Program.

26 (c) (1) The Legislature finds that timely implementation of
27 changes in genetic screening programs and continuous maintenance
28 of quality statewide services requires expeditious regulatory and
29 administrative procedures to obtain the most cost-effective
30 electronic data processing, hardware, software services, testing
31 equipment, and testing and followup services.

32 (2) The expenditure of funds from the Genetic Disease Testing
33 Fund for these purposes shall not be subject to Section 12102 of,
34 and Chapter 2 (commencing with Section 10290) of Part 2 of
35 Division 2 of, the Public Contract Code, or to Division 25.2
36 ~~(commencing with Section 38070)~~. *(commencing with Section*
37 *38070) of this code.* The department shall provide the Department
38 of Finance with documentation that equipment and services have
39 been obtained at the lowest cost consistent with technical
40 requirements for a comprehensive high-quality program.

(3) The expenditure of funds from the Genetic Disease Testing Fund for implementation of the Tandem Mass Spectrometry screening for fatty acid oxidation, amino acid, and organic acid disorders, and screening for congenital adrenal hyperplasia may be implemented through the amendment of the Genetic Disease Branch Screening Information System contracts and shall not be subject to Chapter 3 (commencing with Section 12100) of Part 2 of Division 2 of the Public Contract Code, Article 4 (commencing with Section 19130) of Chapter 5 of Part 2 of Division 5 of Title 2 of the Government Code, and any policies, procedures, regulations, or manuals authorized by those laws.

(4) The expenditure of funds from the Genetic Disease Testing Fund for the expansion of the Genetic Disease Branch Screening Information System to include cystic fibrosis, biotinidase, severe combined immunodeficiency (SCID), ~~and adrenoleukodystrophy (ALD) and any other disease;~~ *(ALD), and any other disease that is detectable in blood samples*, as specified in subdivision (d) of Section 125001, may be implemented through the amendment of the Genetic Disease Branch Screening Information System contracts, and shall not be subject to Chapter 2 (commencing with Section 10290) or Chapter 3 (commencing with Section 12100) of Part 2 of Division 2 of the Public Contract Code, Article 4 (commencing with Section 19130) of Chapter 5 of Part 2 of Division 5 of Title 2 of the Government Code, or Sections 4800 to 5180, inclusive, of the State Administrative Manual as they relate to approval of information technology projects or approval of increases in the duration or costs of information technology projects. This paragraph shall apply to the design, development, and implementation of the expansion, and to the maintenance and operation of the Genetic Disease Branch Screening Information System, including change requests, once the expansion is implemented.

(d) (1) The department may adopt emergency regulations to implement and make specific this chapter in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. For the purposes of the Administrative Procedure Act, the adoption of regulations shall be deemed an emergency and necessary for the immediate preservation of the public peace, health and safety, or general welfare. Notwithstanding Chapter 3.5 (commencing with Section

1 11340) of Part 1 of Division 3 of Title 2 of the Government Code,
2 these emergency regulations shall not be subject to the review and
3 approval of the Office of Administrative Law. Notwithstanding
4 Sections 11346.1 and 11349.6 of the Government Code, the
5 department shall submit these regulations directly to the Secretary
6 of State for filing. The regulations shall become effective
7 immediately upon filing by the Secretary of State. Regulations
8 shall be subject to public hearing within 120 days of filing with
9 the Secretary of State and shall comply with Sections 11346.8 and
10 11346.9 of the Government Code or shall be repealed.

11 (2) The Office of Administrative Law shall provide for the
12 printing and publication of these regulations in the California Code
13 of Regulations. Notwithstanding Chapter 3.5 (commencing with
14 Section 11340) of Part 1 of Division 3 of Title 2 of the Government
15 Code, the regulations adopted pursuant to this chapter shall not be
16 repealed by the Office of Administrative Law and shall remain in
17 effect until revised or repealed by the department.

18 (3) The Legislature finds and declares that the health and safety
19 of California newborns is in part dependent on an effective and
20 adequately staffed genetic disease program, the cost of which shall
21 be supported by the fees generated by the program.

22 SEC. 2. Section 125001 of the Health and Safety Code is
23 amended to read:

24 125001. (a) The department shall establish a program for the
25 development, provision, and evaluation of genetic disease testing,
26 and may provide laboratory testing facilities or make grants to,
27 contract with, or make payments to, any laboratory that it deems
28 qualified and cost effective to conduct testing or with any metabolic
29 specialty clinic to provide necessary treatment with qualified
30 specialists. The program shall provide genetic screening and
31 followup services for persons who have the screening.

32 (b) The department shall expand statewide screening of
33 newborns to include tandem mass spectrometry screening for fatty
34 acid oxidation, amino acid, organic acid disorders, and congenital
35 adrenal hyperplasia as soon as possible. The department shall
36 provide information with respect to these disorders and available
37 testing resources to all women receiving prenatal care and to all
38 women admitted to a hospital for delivery. If the department is
39 unable to provide this statewide screening by August 1, 2005, the
40 department shall temporarily obtain these testing services through

1 a competitive bid process from one or more public or private
2 laboratories that meet the department's requirements for testing,
3 quality assurance, and reporting. If the department determines that
4 contracting for these services is more cost effective, and meets the
5 other requirements of this chapter, than purchasing the tandem
6 mass spectrometry equipment themselves, the department shall
7 contract with one or more public or private laboratories.

8 (c) The department shall expand statewide screening of
9 newborns to include screening for severe combined
10 immunodeficiency (SCID) as soon as possible. In implementing
11 the SCID screening test, the department shall also screen for other
12 T-cell lymphopenias that are detectable as a result of screening
13 for SCID, insofar as it does not require additional costs or
14 equipment beyond that needed to test for SCID.

15 (d) The department shall expand statewide screening of
16 newborns to include screening for adrenoleukodystrophy (ALD)
17 and any other disease *that is detectable in blood samples* as soon
18 as the disease is adopted by the federal Recommended Uniform
19 Screening Panel (RUSP).